Evidence-Based Medicine & Clinical Practice Guidelines

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Evidence-Based Medicine & Clinical Practice Guidelines

Objectives

At the end of this lecture, students will be able to articulate an understanding of

- **Evidence-based medicine**
  - **What it is**
  - **Why it was developed**
  - **What is its impact**
- **Clinical practice guidelines**
  - **Description**
  - **Their purpose**
  - **Their**
    - **Development**
    - **Implementation**
    - **Assessment**

Evidence-based Medicine
The Beginning

- Philosophical origins extend back to mid-19th century Paris
- Began at Kaiser Permanente
  - Mid 80s
  - David Eddy credited with coining the term EBM
- Premise
  - Clinical decisions should be based on
    - Results of peer-reviewed clinical experimentation and randomized controlled trials
  - Rather than on
    - Observational studies, logical intuition, personal experience and expert opinion.

Evidence-based Medicine
Why?

- The usual sources of clinical advice, expert opinions, have proven variable and unreliable
- There is tremendous geographic variation in the use of some diagnostic and therapeutic modalities without an evident basis for the variation in the prevalence or incidence of the disease
- There is a gap between practice and evidence
- Costs of medical care in the United States are higher absolutely and proportionally than in any other industrialized country

Berg A; Dimensions of Evidence; Journa
American Board of Family Practice;
http://www.medscape.com/viewarticle/41

Evidence-based Medicine
What Is It?

EBM is

"...the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."

David L Sackett, et al
British Medical Journal, January 13, 1996
(BMJ 1996; 312: 71-20)

Evidence-based Medicine
What Is It?

EBM

- **De-emphasizes intuition, unsystematic clinical experience, expert opinion, collegial relationships, common sense, community standards, and pathophysiologic rational as sufficient grounds for clinical decision-making**

- **Emphasizes examination of evidence from clinical research**

On what evidence is the advice based?

Evidence-based Medicine
What Is It Not?

EBM is

- **The conscientious, explicit and judici**
  current best evidence in making deci
  about the care of individual patients

EBM is not

- **Old-hat nor impossible to practice**
- **“Cook-book” medicine**
- **Cost cutting medicine**
- **Restricted to randomized trials and meta-analyses**

David Sackett, et al; Center for Evidence-Bas
http://www.cebm.net/ebm_is_isnt.asp

Evidence-based Medicine Misconceptions

- ***EBM ignores clinical experience and clinical intuition***
  - **Rather, it is important to expose learners to exceptional clinicians who have a gift for intuitive diagnosis a talent for precise observation and excellent judgment in making difficult management decisions**
- ***Understanding of basic investigation and pathophysiology plays no part in evidence-based medicine***
  - **The dearth of adequate evidence demands that clinical problem-solving must rely on an understanding of underlying pathophysiology**
- ***Evidence-based medicine ignores standard aspects of clinical training such as the physical examination***
  - **A careful history and physical examination provides much, and often the best, evidence for diagnosis and directs treatment decisions**

http://www.cche.net/usersguides/ebm.a
Evidence-Based Medicine; A New Appr
Teaching the Practice of Medicine. Ad
JAMA 1992 Nov 4; 268 (17): 2420-5)

Evidence-based Medicine

Old Clinical Practice Paradigm

- Unsystematic observations from clinical experience are a valid way of building and maintaining one's knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment
- The study and understanding of basic mechanisms of disease and pathophysioogic principles are a sufficient guide for clinical practice
- A combination of thorough traditional medial training and common sense is sufficient to allow one to evaluate new tests and treatment
- Content expertise and clinical experience are a sufficient base from which to generate valid guidelines for clinical practice
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http://www.cche.net/usersguides/ebm.a
Evidence-Based Medicine; A New Appr
Teaching the Practice of Medicine. Ad
JAMA 1992 Nov 4; 268 (17): 2420-5)

Evidence-based Medicine
Clinical Scenarios

- Trust me
- Deferral to authority
- In my experience
- Community standard

Evidence-based Medicine
New Clinical Practice Paradigm

- Clinical experience, and the development of clinical instincts are crucial and necessary parts of becoming a competent physician
- The study and understanding of basic mechanisms of disease are necessary but insufficient guides for clinical practice
  - The rationales for diagnosis and treatment which follow basic pathophysiologic principles may, in fact, be incorrect...
- Understanding certain rules of evidence is necessary to correctly interpret literature on causation, prognosis, diagnostic tests, and treatment strategy

http://www.cche.net/usersguides/ebm.a
Evidence-Based Medicine; A New Appr
Teaching the Practice of Medicine. Ad
JAMA 1992 Nov 4; 268 (17): 2420-5)

Evidence-based Medicine
What Is It?

"Medicine, long recognized as a subtle admixture of science and art, has moved notably in the direction of an exact science as new tools and techniques have been developed to help practitioners of "the healing arts" understand better what works in the treatment of patients.

This dramatic expansion of medical knowledge, and of the ways by which medial knowledge is advanced, is changing the face of medical practice"

Arnold Rosoff: Evidence-Based medicine and the Law
The Courts Confront Clinical Practice Guidelines;
Journal of health Politics, Policy and Law, Vol. 26, No

Evidence-based Medicine
How Is It Implemented?

Through Clinical Practice Guidelines

Clinical Practice Guidelines
What Are They?

Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances

Said a bit differently…..to help practitioner patients decide on appropriate healthcare clinical conditions and/or circumstances

Institute of Medicine,

Clinical Practice Guidelines
Basic Types

- Consensus
- Evidence-based
- Data-driven

Clinical Practice Guidelines
Basic Types

- Consensus
- Evidence-based
- Data-driven

Clinical Practice Guidelines
What Are They Not?

- **Protocols**
  - **Rigid statements allowing little or no flexibility or variation**
    - **Set out a precise sequence of activities to be adhered to in the management of a specific clinical condition**
- **Care pathways**
  - **Determine locally agreed to, multidisciplinary practice, based on guidelines and evidence where available , for a specific patient/client group**
    - **Form the medical record**
    - **Help to evaluate outcomes**

Clinical Practice Guidelines
What Should They Do?

Improve the quality of health care in particular clinical settings and circumstances by fostering

- **Reductions in the number of unnecessary or harmful interventions**
- **Provision of treatment options with maximum benefit**
- **Provision of treatments/interventions with minimum risk**
- **Within a framework of acceptable financial cost**

Guidelines for the development and implementation of clinical practice guidelines; http://www.health.gov.au/nhmrc/publications/synopse

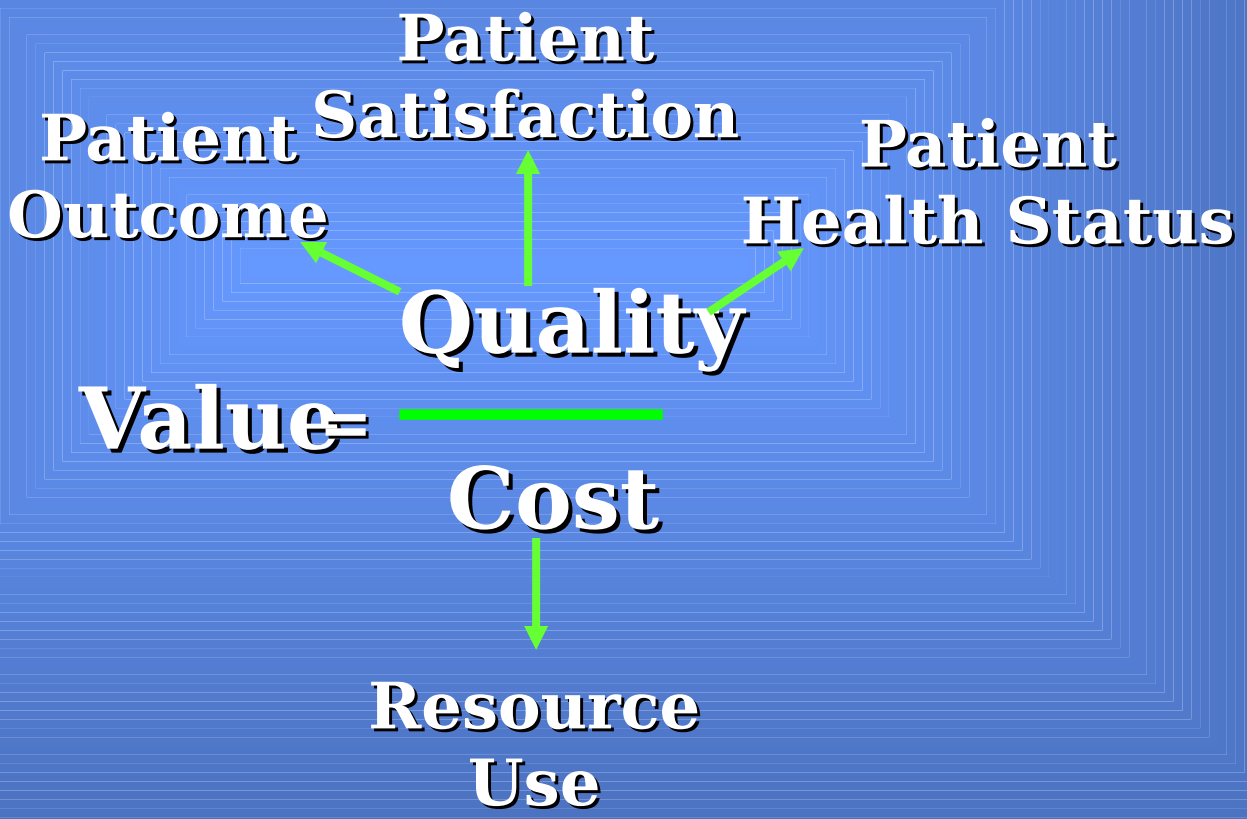
Clinical Practice Guidelines
What Are They Again?

Systematically developed statements
improve clinical decision-making in c

- Improve processes of care
- Reduce unjustifiable variation caused by
  - Lack of knowledge
  - New treatments and technology
  - Uncertainty
  - Habit
  - Experience
  - Deference
- Improve patient outcome
- Improve cost-effectiveness

Evidence-Based Medicine & Clinical Practice Guidelines

Health Care Value



Clinical Practice Guidelines
How Many Are There?

- 1800 developed by 75 groups

American Medical Association http://www.ama-assn.org/ama/bub/article/2943-3246.htm

- 886 guidelines addressing diseases
  - Signs and symptoms 198
  - Nervous system diseases 172
  - Cardiovascular diseases 168
  - Parasitic diseases 20
- 95 guidelines addressing mental disorders

National Guideline Clearin
http://www.guideline.gov

Clinical Practice Guidelines
NGC Inclusion Criteria

- Contains systematically developed statements that include recommendations, strategies, or information that assists (providers) in making decisions about appropriate health care for specific clinical circumstances
- Was produced under the auspices of medical specialty associations, relevant professional societies, public or private organizations, government agencies, or health care organizations or plans
- Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development
- Was developed reviewed, or revised within the last five years

Clinical Practice Guidelines
Attributes

- Valid
- Reproducible
- Cost-effective
- Representative/multidisciplinary
- Clinically applicable
- Flexible
- Clear
- Reviewable
- Amenable to clinical audit

Clinical Practice Guidelines

What Makes a Good Guideline?

Good CPGs can

- Change clinical practice and influence patient outcome
  - Increase knowledge
  - Change attitudes
  - Change behavior
- Actually be implemented and used
- Provide extensive, critical, and well-balanced information on the benefits and limitations of various clinical interventions

Applying guidelines to the care of an individual patient always

Clinical Practice Guidelines

When is Development Appropriate?

- Clinically important affecting large numbers of people with substantial morbidity or mortality
- Complex enough to initiate debate about the recommendations
- Evidence of variation between actual and appropriate care
- No existing valid guidelines available to use
- Is an adequate amount of existing evidence available
- Recommendation will be acceptable to the potential users
- Implementation is feasible

Clinical Practice Guidelines
Development

Development often requires acquiring new skills

- **Appraising and grading evidence from the literature**
  - **Study validity**
  - **Applicability**
- **Team facilitation**
- **Data analysis**

Clinical Practice Guidelines Development

- Identification of goals and objectives
- Developing an evidence model
- Literature search for evidence
- Literature synthesis with directional assessment
- Analytical preparation
- Analytical model
- Guideline recommendations

R Connis, et al; The Development of Evidence-Based Clinical practic
International Journal of Technology Assessment in Health Care, 16

Clinical Practice Guidelines
Implementation

"Unless research-based evidence and guidance is incorporated into practice, efforts to improve the quality of care will be wasted.

Implementing evidence may require health professionals to change long-held patterns of behavior."

(p1) Effective Health Care Bulletin, 1999

Clinical Practice Guidelines
Implementation

Key implementation questions

- **Why are practitioners practicing as they do?**
- **Why might they not practice according to the new guidelines?**

These questions imply a number of "implementation" skills

Clinical Practice Guidelines
Implementation Skills

Successful CPG implementation will likely require

- **Knowledge of the basis of behavior change in healthcare practitioners**
- **Knowledge of current clinical practice**
- **Identification of barriers to change**
- **Empirical evidence about the effectiveness of different dissemination and implementation strategies**
- **Knowledge of methods of guideline development**
- **Appraisal skills related to the monitoring of guideline uses**
  - **Data collection**
  - **Data processing**
  - **Data analysis**
- **Teaching/education skills**

Clinical Practice Guidelines Implementation Strategies

- Range from simple and low cost
  - Posting in local publications
  - Publication in professional journals
  - Presentations
- To multi-faceted
  - Outside consultants
  - Marketing strategies
  - Computer/software solutions

Clinical Practice Guidelines
Implementation

Strategies

Strategies hypothesized to be effective

- **Local adaptation**
- **Audit and feedback**
- **Face to face educational outreach/visitation using opinion leaders**
- **Computer (paper-based) Decision Support Systems**
- **Patient education**

E McKinley, et al; Clinical Practice Guidelines, A Selective Li
Prepared for the New Zealand Guidelines Group; March 2001

Clinical Practice Guidelines
Implementation

Barriers to implementation

- Knowledge
- Skills
- Attitudes
- Habits
- Threats to income
- Turf
- Workload
- Fear

Clinical Practice Guidelines
Assessment

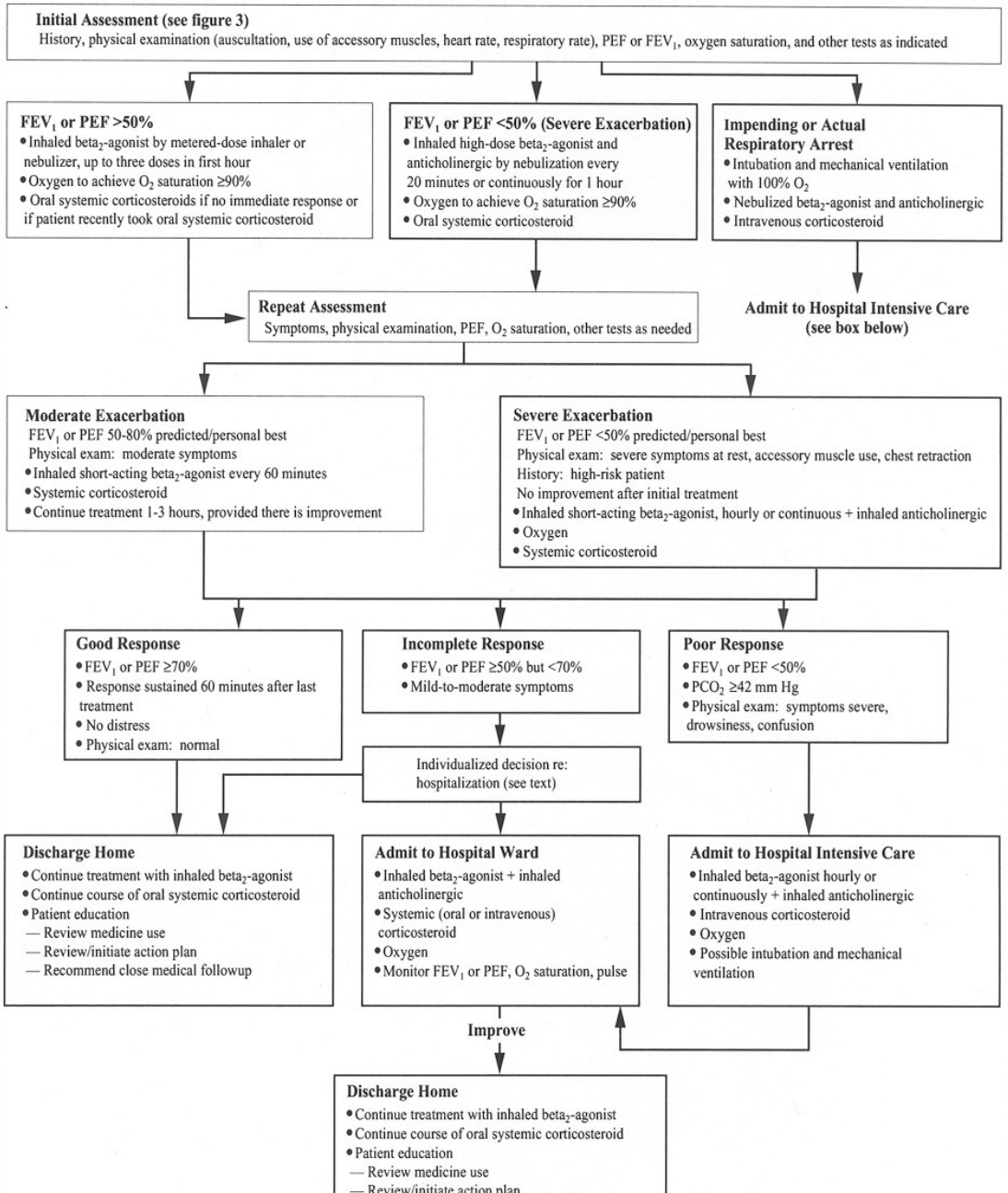
How can we assess the impact of guidelines?

By measuring

Clinical Practice Guidelines
Assessment

- By measuring
  - Patient outcome
  - Patient satisfaction
  - Patient health status
  - Cost/resource use

FIGURE 3-11. MANAGEMENT OF ASTHMA EXACERBATIONS: EMERGENCY DEPARTMENT AND HOSPITAL-BASED CARE


Initial Assessment (see figure 3)
History, physical examination (auscultation, use of accessory muscles, heart rate, respiratory rate), PEF or FEV1, oxygen saturation, and other tests as indicated
FEV1 or PEF >50%
• Inhaled beta2-agonist by metered-dose inhaler or nebulizer, up to three doses in first hour
• Oxygen to achieve O2 saturation ≥90%
• Oral systemic corticosteroids if no immediate response or if patient recently took oral systemic corticosteroid
FEV1 or PEF <50% (Severe Exacerbation)
• Inhaled high-dose beta2-agonist and anticholinergic by nebulization every 20 minutes or continuously for 1 hour
• Oxygen to achieve O2 saturation ≥90%
• Oral systemic corticosteroid
Impending or Actual Respiratory Arrest
• Intubation and mechanical ventilation with 100% O2
• Nebulized beta2-agonist and anticholinergic
• Intravenous corticosteroid
Repeat Assessment
Symptoms, physical examination, PEF, O2 saturation, other tests as needed
Admit to Hospital Intensive Care (see box below)
Moderate Exacerbation
FEV1 or PEF 50-80% predicted/personal best
Physical exam: moderate symptoms
• Inhaled short-acting beta2-agonist every 60 minutes
• Systemic corticosteroid
• Continue treatment 1-3 hours, provided there is improvement
Severe Exacerbation
FEV1 or PEF <50% predicted/personal best
Physical exam: severe symptoms at rest, accessory muscle use, chest retraction
History: high-risk patient
No improvement after initial treatment
• Inhaled short-acting beta2-agonist, hourly or continuous + inhaled anticholinergic
• Oxygen
• Systemic corticosteroid
Good Response
• FEV1 or PEF ≥70%
• Response sustained 60 minutes after last treatment
• No distress
• Physical exam: normal
Incomplete Response
• FEV1 or PEF ≥50% but <70%
• Mild-to-moderate symptoms
Poor Response
• FEV1 or PEF <50%
• PCO2 ≥42 mm Hg
• Physical exam: symptoms severe, drowsiness, confusion
Individualized decision re: hospitalization (see text)
Discharge Home
• Continue treatment with inhaled beta2-agonist
• Continue course of oral systemic corticosteroid
• Patient education
— Review medicine use
— Review/initiate action plan
— Recommend close medical followup
Admit to Hospital Ward
• Inhaled beta2-agonist + inhaled anticholinergic
• Systemic (oral or intravenous) corticosteroid
• Oxygen
• Monitor FEV1 or PEF, O2 saturation, pulse
Admit to Hospital Intensive Care
• Inhaled beta2-agonist hourly or continuously + inhaled anticholinergic
• Intravenous corticosteroid
• Oxygen
• Possible intubation and mechanical ventilation
Improve
Discharge Home
• Continue treatment with inhaled beta2-agonist
• Continue course of oral systemic corticosteroid
• Patient education
— Review medicine use
— Review/initiate action plan

Clinical Practice Guidelines
Assessment
Linking Guidelines to Measures

- Outcomes
  - Clinical Measures
    - Improvement in pulmonary function
      - Peak expiratory flow
        - » Predicted vs. personal best
        - » Variability
      - Spirometry
        - » FEF25-75
        - » FEV1
  - Reduction in frequency of exacerbations
    - Reduced incidence of urgent care requirements
      - At physician's office
      - In emergency department
    - Reduced frequency of hospitalization

http://www.nhlbisupport.com/asthma/research

Clinical Practice Guidelines
Assessment
Linking Guidelines to Measures

- **Outcomes**
  - **Clinical Measures**
    - **Reduction in medication usage**
      - **Reduced use of rescue medication**
        - **Reduced use of beta2-agonists**
      - **Reduced use of steroids**
        - **Reduced use of oral steroids**
        - **Reduction in dosage of inhaled steroids**

Evidence-based Medicine
Assessment

- 55 of 59 published evaluations of guidelines detected significant improvements in the process of care
- 9 of 11 studies that evaluated patient outcome reported significant improvements

  Grimshaw J, et al; Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet 1993;342:1317-22
- 14 of 18 studies of computer-based guidelines found improved provider “adherence” with the guideline
- 3 of 8 of these studies that looked at outcomes found improvements

  Shiffman R, et al;Computer-based guideline impelntatinon systems: a systematic review of functionality and effectiveness; J Am Med Inform Assoc 1999;6:104-14